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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,409	06/30/2003	Steven M. Fischer	10010632-3	1968

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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11/01/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary	Application No. 10/611,409	Applicant(s) FISCHER, STEVEN M.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-34, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-34, 42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 8/17/07 to the Office action has been entered. Claims 21-24 and 42-43 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation "wherein said extension product is not separated from said single stranded template nucleic acid" has no support in the specification because in the specification, it discloses that prior to cleavage of the tag from the extended base on the DNA template, the excess, unincorporated cdNTPs are preferably removed from the extension reaction, the tags may

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be removed by any of a variety of washing or rinsing procedures that separate the excess, unincorporated dNTPs from the extended DNA template, and in one preferred embodiment, the extension reaction is contained within a chamber that has an attached filtration membrane, e.g., an ultrafiltration membrane, that allows small molecules such as water, salts, and cdNTPs to pass through, while retaining large molecules such as ssDNA (See pg. 3 [0018], [0030], [0048]. [0049] of US 2004/0033522). By doing so, the extension products are separated from said single stranded template nucleic acid. There is no support that said extension product is not separated from said single stranded template nucleic acid. Thus, the new limitation constitutes a new matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-31, 33-34 and 42-43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (WO 99/02728, issued January 21, 1999).

Schmidt et al. disclose that in one arrangement, a series of DNA fragments is provided by contacting a template in the presence of DNA polymerase with a mixture of nucleotides sufficient for hybridizing to the template for forming a second strand of DNA complementary to the template. The mixture comprises a set of four probes containing all four nucleotides for hybridizing to the template in which the nucleotide of each probe comprises a modified nucleotide, which is capable of polymerizing to the second strand of DNA, but blocked to

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prevent further polymerization and which is cleavably attached to the mass label. The mass label is identified by mass spectrometry for the modified nucleotide (See pg. 3, paragraph 5 and pg. 4, paragraph 1). The mass label is corresponding to a modified nucleotide so that the nucleotide present in the target template may be deduced (See pg. Paragraph 4). The cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). Ligating is also used to produce extended products (See pg. 12, paragraph 1 and 3). The cleavable tag is a 3' cleavable tag (See pg. 46, paragraph 5, fig. 4a and fig. 13) in which the cleavable tag is attached to the 3' end.

Schmidt et al. do not explicitly disclose the cleavable tag is an acid or base cleavable tag as recited in claims 29 and 30. However, Schmidt et al. disclose that the cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). This teaching is inherent that the cleavable tag is an acid or base cleavable tag. Thus, the teachings of Schmidt et al. anticipate the limitations of Schmidt et al.

The response discussed the definition of the extension product. The response further argues that Schmidt et al. teach dissociation of the extension product from the template nucleic acid to produce a population of single stranded extension products, which are washed in a single step. However, this limitation discussed herein is not recited by the claims.

The response also argues that Schmidt et al. do not teach the element of cleaving the tag from "an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence". However, based upon the teachings set forth above, Schmidt et al. disclose the steps (a)-(d) (See fig. 3). Thus, the rejection is maintained.

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6. Claim 32 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (WO 99/02728, issued January 21, 1999) as applied to claims 21-31, and 33-34 in view of Cheeseman et al. (5,302,509, issued Apr. 12, 1994).

The teachings of Schmidt et al. are set forth in section 5 above. Schmidt et al do not disclose that the cleavable tag is a fluorescent tag.

Cheeseman et al. disclose a method for determining the sequence of nucleotides on a single strand DNA in which the cleavable tag is a fluorescent tag (See column 2, lines 57-59 and column 6, lines 11-13).

One of ordinary skill in the art would have been motivated to apply a fluorescent tag for the cleavable tag because Cheeseman et al. apply fluorescence ⁱⁿ a cleavable tag for nucleic acid sequencing. It would have been prima facie obvious to apply a fluorescent tag for the cleavable tag for nucleic acid sequencing.

The response does not have a specific argument regarding the rejection. With the same reasons as set forth in section 5 above, the rejection is maintained.

Summary

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung *J. Tung*
October 23, 2007

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

10/25/07